

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 29 and 31 are amended currently, and claims 1-28, 30, and 32-42 are slated for cancellation. Upon entry of this response, therefore, claims 29 and 31 will be pending.

Amended claims 29 and 31 recite an expression vector not disclosed by any combination of the prior art

Claims 29 and 31 stand rejected under 35 USC § 103(a) over De Mot *et al.* in view of each Takano *et al.*, Whyte *et al.*, and Chiu *et al.* The stated grounds for this rejection are inapposite to the present claims, however.

The claims recite the *TipA*-LG10 gene promoter sequence, as supported, for example, on page 15 of the specification, at lines 14 and 15, page 33, at lines 9–12 and in Figures 9 and 23. The *TipA*-LG10 promoter is a hybrid promoter, comprising the *TipA*-gene promoter sequence and a binding site derived from lambda phage *gene10*. No cited reference discloses the *TipA*-LG10 promoter, nor does any combination of teachings reasonably gleaned from the references render the promoter sequence obvious. The cited art does not substantiate a *prima facie* case under Section 103, therefore, and the present rejection should be withdrawn.

Amended claims 29 and 31 recite an expression vector that is advantageous for protein production

According to the examiner, no evidence of record establishes an unexpected property or advantage associated with an illustrative expression vector of the claimed invention, pTIP-LNH1/SEQ ID NO: 110. See office action, page 5. Applicants disagree.

Applicants would emphasize that their claimed expression vector, having a *TipA*-LG10 promoter, achieves an unexpectedly high level of protein production at low temperatures (4°C) relative to other vectors using wild-type promoters. See paragraph [0202] of the published version and data presented in Figure 19. Protein production at low temperature is desirable, because at low temperatures, proteins are more soluble and less likely to aggregate, thus forming inclusion bodies. In conventional expression systems,

however, the quantity of protein produced is greatly reduced at low temperatures. See published specification on page 15, at lines 12–29. Surprisingly, applicants' invention solves this problem due to unprecedented expression levels effected at low temperatures that confounded conventional technology.

Thus, expression vectors of the claimed invention, comprised of a *TipA*-LG10 promoter, yield at 4°C from about 8.9 to > 390 times the amount of protein produced with the wild-type promoter (see Figure 19). Nothing in the prior art could have suggested how to achieve this improvement.

It would be erroneous to deny patentable weight to these data. According to the PTO's own rules,

[w]hen an applicant submits evidence, whether *in the specification as originally filed* or in reply to a rejection, *the examiner must reconsider the patentability of the claimed invention*. The decision on patentability must be made based upon consideration of all the evidence, including the evidence submitted by the examiner and the evidence submitted by the applicant.

MPEP § 2142 (emphasis added). As demonstrated above, applicants' specification evidences unexpectedly high levels of protein achieved, at low temperatures, with the claimed invention. For this reason, too, the pending obviousness rejection warrants reconsideration and withdrawal.

CONCLUSION


Applicants submit that the present application is in condition for allowance, and they request an early indication to this effect. Examiner Popa is invited to contact the undersigned directly, should she feel that some issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 CFR §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, Applicants hereby petition for such

extension under 37 CFR § 1.136 and authorize payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

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By 

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicants
Registration No. 29,768